

New Jersey Department of Health and Senior Services

RTK Substance number: 1507

HAZARDOUS SUBSTANCE FACT SHEET

Common Name: PHENYTOIN

CAS Number: 57-41-0 DOT Number: None

DOT Number: None Date: April 2001

HAZARD SUMMARY

* **Phenytoin** can affect you when breathed in.

- * **Phenytoin** is a CARCINOGEN--HANDLE WITH EXTREME CAUTION.
- * **Phenytoin** is a TERATOGEN--HANDLE WITH EXTREME CAUTION.
- * Phenytoin can cause nausea, vomiting, headache, drowsiness, tremors, confusion, oscillating movements of the eyeballs (nystagmus), and blurred vision.
- * High or repeated exposures to **Phenytoin** can cause anemia.
- * Phenytoin may cause a skin allergy. If allergy develops, very low future exposure can cause itching and a skin rash.
- * **Phenytoin** may damage the liver and kidneys.
- * Phenytoin may damage the nervous system causing numbness, "pins and needles," and/or weakness in the hands and feet.

IDENTIFICATION

Phenytoin is a white powder with a bitter taste. It is used as an anti-convulsant medication.

REASON FOR CITATION

- * **Phenytoin** is on the Hazardous Substance List because it is cited by NTP and IARC.
- * This chemical is on the Special Health Hazard Substance List because it is a **CARCINOGEN** and **TERATOGEN**.
- * Definitions are provided on page 5.

HOW TO DETERMINE IF YOU ARE BEING EXPOSED

The New Jersey Right to Know Act requires most employers to label chemicals in the workplace and requires public employers to provide their employees with information and training concerning chemical hazards and controls. The federal OSHA Hazard Communication Standard, 1910.1200, requires private employers to provide similar training and information to their employees.

- * Exposure to hazardous substances should be routinely evaluated. This may include collecting personal and area air samples. You can obtain copies of sampling results from your employer. You have a legal right to this information under OSHA 1910.1020.
- * If you think you are experiencing any work-related health problems, see a doctor trained to recognize occupational diseases. Take this Fact Sheet with you.

WORKPLACE EXPOSURE LIMITS

No occupational exposure limits have been established for **Phenytoin**. This does not mean that this substance is not harmful. Safe work practices should always be followed.

WAYS OF REDUCING EXPOSURE

- * Enclose operations and use local exhaust ventilation at the site of chemical release. If local exhaust ventilation or enclosure is not used, respirators should be worn.
- * A regulated, marked area should be established where **Phenytoin** is handled, used, or stored.
- * Wear protective work clothing.
- * Wash thoroughly <u>immediately</u> after exposure to **Phenytoin** and at the end of the workshift.
- * The FDA (Food and Drug Administration) has set standards for Good Manufacturing Practices for Drugs and Pharmaceuticals. These should be followed for your protection as well as product quality. See the FDA regulation 21 CFR 210.
- * Post hazard and warning information in the work area. In addition, as part of an ongoing education and training effort, communicate all information on the health and safety hazards of **Phenytoin** to potentially exposed workers.

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This Fact Sheet is a summary source of information of <u>all</u> <u>potential</u> and most severe health hazards that may result from exposure. Duration of exposure, concentration of the substance and other factors will affect your susceptibility to any of the potential effects described below.

HEALTH HAZARD INFORMATION

Acute Health Effects

The following acute (short-term) health effects may occur immediately or shortly after exposure to **Phenytoin**:

* Phenytoin can cause nausea, vomiting, headache, drowsiness, tremors, confusion, oscillating movements of the eyeballs (nystagmus), and blurred vision.

Chronic Health Effects

The following chronic (long-term) health effects can occur at some time after exposure to **Phenytoin** and can last for months or years:

Cancer Hazard

- * Phenytoin is a PROBABLE CARCINOGEN in humans. There is some evidence that it causes brain tumors in humans and animals.
- * Many scientists believe there is no safe level of exposure to a carcinogen.

Reproductive Hazard

* **Phenytoin** is a PROBABLE TERATOGEN in humans.

Other Long-Term Effects

- * High or repeated exposures to **Phenytoin** can cause anemia.
- * **Phenytoin** may cause a skin allergy. If allergy develops, very low future exposure can cause itching and a skin rash.
- * **Phenytoin** may damage the liver and kidneys.
- * Phenytoin may damage the nervous system causing numbness, "pins and needles," and/or weakness in the hands and feet.

MEDICAL

Medical Testing

If symptoms develop or overexposure is suspected, the following are recommended:

- * Complete blood count.
- * Liver and kidney function tests.
- * Evaluation by a qualified allergist, including careful exposure history and special testing, may help diagnose skin allergy.
- * Exam of the nervous system.

Any evaluation should include a careful history of past and present symptoms with an exam. Medical tests that look for damage already done are <u>not</u> a substitute for controlling exposure.

Request copies of your medical testing. You have a legal right to this information under OSHA 1910.1020.

Mixed Exposures

* Because more than light alcohol consumption can cause liver damage, drinking alcohol can increase the liver damage caused by **Phenytoin**.

WORKPLACE CONTROLS AND PRACTICES

Unless a less toxic chemical can be substituted for a hazardous substance, **ENGINEERING CONTROLS** are the most effective way of reducing exposure. The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

In evaluating the controls present in your workplace, consider: (1) how hazardous the substance is, (2) how much of the substance is released into the workplace and (3) whether harmful skin or eye contact could occur. Special controls should be in place for highly toxic chemicals or when significant skin, eye, or breathing exposures are possible.

In addition, the following controls are recommended:

- * Where possible, automatically transfer **Phenytoin** from drums or other storage containers to process containers.
- * A Class I, Type B, biological safety hood should be used when mixing, handling, or preparing **Phenytoin**.

Good **WORK PRACTICES** can help to reduce hazardous exposures. The following work practices are recommended:

- * Workers whose clothing has been contaminated by **Phenytoin** should change into clean clothing promptly.
- * Do not take contaminated work clothes home. Family members could be exposed.
- * Contaminated work clothes should be laundered by individuals who have been informed of the hazards of exposure to **Phenytoin**.
- * Eye wash fountains should be provided in the immediate work area for emergency use.
- * If there is the possibility of skin exposure, emergency shower facilities should be provided.
- * On skin contact with **Phenytoin**, immediately wash or shower to remove the chemical. At the end of the workshift, wash any areas of the body that may have contacted **Phenytoin**, whether or not known skin contact has occurred.
- Do not eat, smoke, or drink where **Phenytoin** is handled, processed, or stored, since the chemical can be swallowed. Wash hands carefully before eating, drinking, smoking, or using the toilet.
- * Use a vacuum or a wet method to reduce dust during cleanup. DO NOT DRY SWEEP.
- * When vacuuming, a high efficiency particulate air (HEPA) filter should be used, <u>not</u> a standard shop vacuum.

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PERSONAL PROTECTIVE EQUIPMENT

WORKPLACE CONTROLS ARE BETTER THAN PERSONAL PROTECTIVE EQUIPMENT. However, for some jobs (such as outside work, confined space entry, jobs done only once in a while, or jobs done while workplace controls are being installed), personal protective equipment may be appropriate.

OSHA 1910.132 requires employers to determine the appropriate personal protective equipment for each hazard and to train employees on how and when to use protective equipment.

The following recommendations are only guidelines and may not apply to every situation.

Clothing

- * Avoid skin contact with **Phenytoin**. Wear protective gloves and clothing. Safety equipment suppliers/manufacturers can provide recommendations on the most protective glove/clothing material for your operation.
- * All protective clothing (suits, gloves, footwear, headgear) should be clean, available each day, and put on before work.

Eve Protection

* Eye protection is included in the recommended respiratory protection.

Respiratory Protection IMPROPER USE OF RESPIRATORS IS DANGEROUS.

Such equipment should only be used if the employer has a written program that takes into account workplace conditions, requirements for worker training, respirator fit testing and medical exams, as described in OSHA 1910.134.

* At <u>any</u> exposure level, use a MSHA/NIOSH approved supplied-air respirator with a full facepiece operated in a pressure-demand or other positive-pressure mode. For increased protection use in combination with an auxiliary self-contained breathing apparatus operated in a pressure-demand or other positive-pressure mode.

QUESTIONS AND ANSWERS

- Q: If I have acute health effects, will I later get chronic health
- A: Not always. Most chronic (long-term) effects result from repeated exposures to a chemical.
- Q: Can I get long-term effects without ever having short-term effects?
- A: Yes, because long-term effects can occur from repeated exposures to a chemical at levels not high enough to make you immediately sick.

- Q: What are my chances of getting sick when I have been exposed to chemicals?
- A: The likelihood of becoming sick from chemicals is increased as the amount of exposure increases. This is determined by the length of time and the amount of material to which someone is exposed.
- Q: When are higher exposures more likely?
- A: Conditions which increase risk of exposure include <u>dust releasing operations</u> (grinding, mixing, blasting, dumping, etc.), <u>other physical and mechanical processes</u> (heating, pouring, spraying, spills and evaporation from large surface areas such as open containers), and <u>"confined space" exposures</u> (working inside vats, reactors, boilers, small rooms, etc.).
- Q: Is the risk of getting sick higher for workers than for community residents?
- A: Yes. Exposures in the community, except possibly in cases of fires or spills, are usually much lower than those found in the workplace. However, people in the community may be exposed to contaminated water as well as to chemicals in the air over long periods. This may be a problem for children or people who are already ill.
- Q: Don't all chemicals cause cancer?
- A: No. Most chemicals tested by scientists are not cancercausing.
- Q: Should I be concerned if a chemical causes cancer in animals?
- A: Yes. Most scientists agree that a chemical that causes cancer in animals should be treated as a suspected human carcinogen unless proven otherwise.
- Q: But don't they test animals using much higher levels of a chemical than people usually are exposed to?
- A: Yes. That's so effects can be seen more clearly using fewer animals. But high doses alone don't cause cancer unless it's a cancer agent. In fact, a chemical that causes cancer in animals at high doses could cause cancer in humans exposed to low doses.
- Q: Can men as well as women be affected by chemicals that cause reproductive system damage?
- A: Yes. Some chemicals reduce potency or fertility in both men and women. Some damage <u>sperm</u> and <u>eggs</u>, possibly leading to birth defects.
- Q: Who is at the greatest risk from reproductive hazards?
- A: Pregnant women are at greatest risk from chemicals that harm the developing fetus. However, chemicals may affect the <u>ability</u> to have children, so both men and women of childbearing age are at high risk.

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Q: Should I be concerned if a chemical is a teratogen in animals?

A: Yes. Although some chemicals may affect humans differently than they affect animals, damage to animals suggests that similar damage can occur in humans.

The following information is available from:

New Jersey Department of Health and Senior Services Occupational Health Service PO Box 360 Trenton, NJ 08625-0360 (609) 984-1863 (609) 984-7407 (fax)

Web address: http://www.state.nj.us/health/eoh/odisweb/

Industrial Hygiene Information

Industrial hygienists are available to answer your questions regarding the control of chemical exposures using exhaust ventilation, special work practices, good housekeeping, good hygiene practices, and personal protective equipment including respirators. In addition, they can help to interpret the results of industrial hygiene survey data.

Medical Evaluation

If you think you are becoming sick because of exposure to chemicals at your workplace, you may call personnel at the Department of Health and Senior Services, Occupational Health Service, who can help you find the information you need.

Public Presentations

Presentations and educational programs on occupational health or the Right to Know Act can be organized for labor unions, trade associations and other groups.

Right to Know Information Resources

The Right to Know Infoline (609) 984-2202 can answer questions about the identity and potential health effects of chemicals, list of educational materials in occupational health, references used to prepare the Fact Sheets, preparation of the Right to Know Survey, education and training programs, labeling requirements, and general information regarding the Right to Know Act. Violations of the law should be reported to (609) 984-2202.

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DEFINITIONS

ACGIH is the American Conference of Governmental Industrial Hygienists. It recommends upper limits (called TLVs) for exposure to workplace chemicals.

A **carcinogen** is a substance that causes cancer.

The **CAS number** is assigned by the Chemical Abstracts Service to identify a specific chemical.

A **combustible** substance is a solid, liquid or gas that will burn.

A **corrosive** substance is a gas, liquid or solid that causes irreversible damage to human tissue or containers.

DEP is the New Jersey Department of Environmental Protection.

DOT is the Department of Transportation, the federal agency that regulates the transportation of chemicals.

EPA is the Environmental Protection Agency, the federal agency responsible for regulating environmental hazards.

A **fetus** is an unborn human or animal.

A **flammable** substance is a solid, liquid, vapor or gas that will ignite easily and burn rapidly.

The **flash point** is the temperature at which a liquid or solid gives off vapor that can form a flammable mixture with air.

HHAG is the Human Health Assessment Group of the federal EPA.

IARC is the International Agency for Research on Cancer, a scientific group that classifies chemicals according to their cancer-causing potential.

A **miscible** substance is a liquid or gas that will evenly dissolve in another.

mg/m³ means milligrams of a chemical in a cubic meter of air. It is a measure of concentration (weight/volume).

MSHA is the Mine Safety and Health Administration, the federal agency that regulates mining. It also evaluates and approves respirators.

A **mutagen** is a substance that causes mutations. A **mutation** is a change in the genetic material in a body cell. Mutations can lead to birth defects, miscarriages, or cancer.

NAERG is the North American Emergency Response Guidebook. It was jointly developed by Transport Canada, the United States Department of Transportation and the Secretariat of Communications and Transportation of Mexico. It is a guide for first responders to quickly identify the specific or generic hazards of material involved in a transportation incident, and to protect themselves and the general public during the initial response phase of the incident.

NCI is the National Cancer Institute, a federal agency that determines the cancer-causing potential of chemicals.

NFPA is the National Fire Protection Association. It classifies substances according to their fire and explosion hazard.

NIOSH is the National Institute for Occupational Safety and Health. It tests equipment, evaluates and approves respirators, conducts studies of workplace hazards, and proposes standards to OSHA.

NTP is the National Toxicology Program which tests chemicals and reviews evidence for cancer.

OSHA is the Occupational Safety and Health Administration, which adopts and enforces health and safety standards.

PEOSHA is the Public Employees Occupational Safety and Health Act, a state law which sets PELs for New Jersey public employees.

PIH is a DOT designation for chemicals which are Poison Inhalation Hazards.

ppm means parts of a substance per million parts of air. It is a measure of concentration by volume in air.

A **reactive** substance is a solid, liquid or gas that releases energy under certain conditions.

A **teratogen** is a substance that causes birth defects by damaging the fetus.

TLV is the Threshold Limit Value, the workplace exposure limit recommended by ACGIH.

The **vapor pressure** is a measure of how readily a liquid or a solid mixes with air at its surface. A higher vapor pressure indicates a higher concentration of the substance in air and therefore increases the likelihood of breathing it in.

Common Name: **PHENYTOIN**

DOT Number: None
NAERG Code: No Citation
CAS Number: 57-41-0

Hazard rating	NJDHSS	NFPA
FLAMMABILITY	Not Found	Not Rated
REACTIVITY	Not Found	Not Rated

CARCINOGEN

POISONOUS GASES ARE PRODUCED IN FIRE

Hazard Rating Key: 0=minimal; 1=slight; 2=moderate; 3=serious: 4=severe

FIRE HAZARDS

- * Use dry chemical, CO₂, water spray, alcohol or polymer foam extinguishers.
- * POISONOUS GASES ARE PRODUCED IN FIRE, including Nitrogen Oxides.
- * If employees are expected to fight fires, they must be trained and equipped as stated in OSHA 1910.156.

SPILLS AND EMERGENCIES

If **Phenytoin** is spilled, take the following steps:

- * Evacuate persons not wearing protective equipment from area of spill until clean-up is complete.
- * Collect powdered material in the most convenient and safe manner and deposit in sealed containers.
- * Ventilate and wash area after clean-up is complete.
- * It may be necessary to contain and dispose of **Phenytoin** as a HAZARDOUS WASTE. Contact your state Department of Environmental Protection (DEP) or your regional office of the federal Environmental Protection Agency (EPA) for specific recommendations.
- * If employees are required to clean-up spills, they must be properly trained and equipped. OSHA 1910.120(q) may be applicable.

FOR LARGE SPILLS AND FIRES immediately call your fire department. You can request emergency information from the following:

CHEMTREC: (800) 424-9300

NJDEP HOTLINE: 1-877-WARN-DEP

HANDLING AND STORAGE

- * Prior to working with **Phenytoin** you should be trained on its proper handling and storage.
- * A regulated, marked area should be established where **Phenytoin** is handled, used, or stored.
- * Phenytoin is not compatible with OXIDIZING AGENTS (such as PERCHLORATES, PEROXIDES, PERMAN-GANATES, CHLORATES, NITRATES, CHLORINE, BROMINE and FLUORINE); STRONG ACIDS (such as HYDROCHLORIC, SULFURIC and NITRIC); and STRONG BASES (such as SODIUM HYDROXIDE and POTASSIUM HYDROXIDE).
- * Store in tightly closed containers in a cool, well-ventilated area.

FIRST AID

For POISON INFORMATION call 1-800-222-1222

Eye Contact

* Immediately flush with large amounts of water for at least 15 minutes, occasionally lifting upper and lower lids.

Skin Contact

* Remove contaminated clothing. Wash contaminated skin with soap and water.

Breathing

- * Remove the person from exposure.
- * Begin rescue breathing (using universal precautions) if breathing has stopped and CPR if heart action has stopped.
- * Transfer promptly to a medical facility.

PHYSICAL DATA

Water Solubility: Insoluble

OTHER COMMONLY USED NAMES

Chemical Name:

2,4-Imidazolidinedione, 5,5-Diphenyl-

Other Names:

Zentropil; Dilantin; Diphenylhydantoin; DPH

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NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES

Right to Know Program

PO Box 368, Trenton, NJ 08625-0368 (609) 984-2202